

### **REMARKS**

Claims 1-26 are currently pending in the application, with claims 1, 4-12, 15, 16, 18, 19, 21, 24, and 25 under consideration (claims 2, 3, 13, 14, 17, 20, 22, 23, and 26 having been withdrawn by the Examiner as drawn to non-elected subject matter). Claims 1, 6, 8, 9, 24, and 25 are amended by the present communication. The subject amendments are supported by the specification at, for example, p. 18, ll. 21-24 and p. 22, ll. 28-33, and the claims as originally filed. No new matter is introduced by the present amendments. Upon entry of the present amendment, claims 1, 4-12, 15, 16, 18, 19, 21, 24, and 25 will remain pending and under consideration.

#### **Objection to the Specification**

The objection to the specification as allegedly containing an embedded hyperlink is respectfully traversed. However, in order to reduce the issues and expedite prosecution, the paragraph beginning at page 25, line 19 has been amended to identify the world wide website without a hyperlink. Accordingly, withdrawal of the objection to the specification is respectfully requested.

#### **Priority**

The Examiner asserts that specific reference to the prior-filed applications must be included in the first sentence of the specification, in accordance with MPEP§ 201.11. Provided herein is a paragraph, containing reference to the prior-filed applications, for insertion into the specification immediately after the title. Further, Applicants note that the claim to priority was made within the time period set forth in 37 CFR 1.78(a). Thus, Applicants believe that all requirements have been met in order to receive benefit of priority to all of the referenced applications.

### **Objections to the Claims**

The objection to claim 6 for allegedly containing an informality is respectfully traversed. Specifically, the Examiner asserts that the claim 6 recites “markers markers,” which is awkward. Without acquiescing to the Examiner’s reasoning, claim 6 has been amended herein to delete the second instance of “marker.” Accordingly, reconsideration and withdrawal of this objection are respectfully requested.

### **Rejections under 35 U.S.C. § 101**

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 stand rejected under 35 U.S.C. 101, for allegedly being directed to non-statutory subject matter.

Specifically, the Examiner alleges that the claims are drawn to a process that includes embodiments that are entirely mental steps. The Examiner indicates, however, that the present claims should positively recite the apparatus which accomplishes the method steps would qualify the claims as a statutory process. Without acquiescing to the reasoning offered in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended the claims to positively recite the apparatus used in the claimed method. As amended, claims 1 and 9 recite that the “comparing the zygosity of the markers to a multivariate scoring matrix to obtain a marker score, wherein the multivariate scoring matrix correlates patterns of marker zygosity with probabilities of exhibiting phenotypic attributes, using suitable computer software for use on a computer.” Support for the amendment may be found, for example, at p. 18, ll. 21-24 of the specification as-filed.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are respectfully requested.

### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite. In particular, the Examiner alleges that the term

“zygosity” as recited in claims 1 and 9 is vague and indefinite because it is unclear to what it refers. Applicants submit that the skilled artisan would readily understand the meaning of “zygosity” in the context of the claim. However, without acquiescing to the reasoning offered in the Action, claims 1 and 9 have been amended herein to indicate that “zygosity is heterozygosity or homozygosity for one or more alleles at a locus, or heterozygosity or homozygosity for one or more alleles between chromosomes, or allele heterozygosity among several alleles at a locus on one chromosome.” Support for this amendment may be found in the specification as-filed at, for example, p. 13, ll. 26-30.

The Examiner alleges that the phrase “the characteristic” as recited in claim 9 is vague because it is unclear whether it refers to genomic characteristics or phenotypic characteristics. Without acquiescing to the reasoning offered in the Action, claim 9 has been amended herein to replace “the characteristic” with “the one or more phenotypic characteristics.”

Finally, the Examiner asserts that the phrase “is used for” as recited in claims 24 and 25 is vague because this step is allegedly passive and therefore, it is unclear what active method step is intended to be represented by this limitation. Without acquiescing to the reasoning offered in the Action, claims 24 and 25 have been amended to delete the language at issue.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

### **III. Rejections under 35 U.S.C. § 102**

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Blumenfeld et al. (U.S. Patent No. 6,528,260; hereinafter “Blumenfeld”). Applicants traverse the rejection as applied to the claims as presently amended.

The Examiner asserts that Blumenfeld teaches “a method for determining whether an individual has an enhanced probability of exhibiting a phenotypic attribute,” citing several passages in Blumenfeld (Office Action at p. 12, ll. 1-3). However, a careful review of these passages reveals that each merely teach the details of conducting an association study. For example, col. 9, fourth paragraph merely provides background on “genetic analysis of complex traits” (e.g., linkage analysis); col. 67, third paragraph provides “methods of genotyping an individual for biallelic markers”; col. 80, last two paragraphs provides a description of

“population association studies”; and col. 84 first two paragraphs provides teaching regarding the selection of a population (i.e., affected or trait positive) for examination in an association study. In short, these passages teach the skilled artisan to conduct association studies to identify genes associated with known phenotypes.

Indeed, Blumenfeld reports the results of such studies, which establish an association between particular markers and a known phenotype or trait. Blumenfeld teaches that several approaches may be employed for such studies, for example, a candidate gene approach (Blumenfeld at col. 21, lines 14-17). This approach is based on the identification of genetic markers specifically derived from genes potentially involved in a biological pathway related to the trait of interest. Accordingly, Blumenfeld chose as candidate genes, certain genes involved in drug metabolism (Blumenfeld at col. 21, lines 21-26). Thus, Blumenfeld reports the “discovery of a set of novel DME-related biallelic markers” (Blumenfeld at col. 10, lines 34-35). For example, Blumenfeld reports an association between asthma and the biallelic markers of the MGST-II gene (Example 3), and a further association between the side effects of treatment with the anti-asthmatic drug Zyflo and the identified biallelic markers (Example 4). Thus, the focus of the teachings of Blumenfeld is the elucidation of a gene responsible for a known phenotype.

In contrast, the present invention is directed to methods which interpret an individual’s broad-based genetic profile, wherein the profile includes the individual’s genomic genotype at statistically relevant markers, and predicts the probability of that individual exhibiting particular phenotype(s) from one or more relevant markers. Applicants respectfully submit that Blumenfeld does not disclose the presently claimed methods of deriving the probability a phenotypic characteristic based on an individual’s genotype at a preselected set of markers, markers shown through association and other studies to be linked directly or indirectly to a certain phenotypic characteristic (e.g., a particular disease state), as in claim 1. Rather, Blumenfeld discloses association studies in which a phenotype is linked to a single genotype.

Further, Blumenfeld does not disclose a method of reporting information obtained from an interpretation of an individual’s broad-based genetic profile to that individual (i.e., “evaluating genomic markers from an individual for zygosity at each member of a preselected set of markers”), in which the phenotypic characteristics are subjected selection criteria (i.e.,

“applying one or more selection criteria for each of the one or more phenotypic characteristics”), comparing a multivariate scoring matrix to the marker set to obtain a single risk score for each selected phenotype (i.e., determining whether the marker score indicates an enhanced, diminished, or average probability of exhibiting a phenotypic characteristic”), and combining with other information (e.g., “information that is relevant to the individual’s probability of exhibiting a phenotypic characteristic”), and communicating the results to the individual, for example, in a report (as in claim 9).

Based on the reasons set forth above it is respectfully submitted that the present claims distinguish over Blumenfeld. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the claims are in condition for allowance, and a notice to that effect is respectfully requested.

Please charge \$65.00 to Deposit Account No. 07-1896 to cover a One-Month Extension of Time fee. No other fee is believed to be due in connection with the submission filing of this paper. However, the Commissioner is hereby authorized to charge any other fees associated with this submission, or credit any overpayments, to Deposit Account No. 07-1896.

The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Respectfully submitted,

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